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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,474	06/23/2003	Thomas J. Boyd	IR 7348-02	7254

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,474	BOYD ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Informalities

The following informalities are noted and should be corrected in responding to this Office action:

1) Claim 1, penultimate line, the double comma after "anion" should be deleted and replaced with a semicolon.

2) Claim 7, last line, "10to" should be rewritten as --- 10 to ---

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is incomplete insofar as the variable "n" in the structural formula is not defined.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barton et al (USP 5,695,745) in view of Behan et al (USP 5,185,155).

The primary reference discloses aqueous oral care compositions comprising a cationic antimicrobial agent, e.g., cocoyl arginine ester salt ("CAE"): see the passage bridging the bottom of col. 2 and the top of col. 3; see also working example 1 at the top of col. 9, wherein the amount of CAE used (0.48 percent) falls squarely within the range recited by instant claim 3. The compositions further contain conventional additives including, *inter alia*, nonionic surfactants such as ethoxylated hydrogenated castor oil (a "chremophor": see col. 2, line 42), and silicas (col. 4, last paragraph), which would simultaneously be both abrasives (as explicitly identified therein) and thickeners (when silica gels) as required by instant claims 5 and 6. The primary reference differs from the instant claims insofar as it does not disclose chremphor-precoated silicas.

The secondary reference teaches encapsulating flavors in nonionic-surfactant coated silica particles to provide delayed release (col. 3, lines 40-60). As is clear from the disclosure of col. 2, lines 28-

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30 and column 4, lines 7-11, the flavor and surfactant will be present in substantial excess relative to silica, the amounts corresponding to those recited by instant claim 7. The encapsulated flavors are used, *inter alia*, in toothpaste formulations (see especially working example 22 at col. 7). The secondary reference differs from the instant claims insofar as it does not specifically disclose the use of chremphors, although it does clearly suggest the use of "polyethoxylated fatty alcohols" at col. 3, line 49.

The primary reference includes flavoring agents such as peppermint oil to increase palatability (col. 5, lines 35 et seq). It would have been obvious to have incorporated those flavors into surfactant-coated silica particles in order to provide extended activity as taught by the secondary reference; using those surfactants already at hand, e.g., a chremophor as disclosed by the primary reference at col. 2, line 42, in the interest of economy and expediency would have been self-evident.

2) Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barton et al (USP 5,695,745) in view of Behan et al (USP 5,185,155), the combination being taken further in view of Beltran et al (WO 03/043593).

The primary and secondary references and the rationale for combining them are discussed in subsection "1)" supra. The compositions suggested by their combined teachings differ from the instant claim insofar as the hydrochloric salt of ethyl lauroyl arginine ("LAE") is not specifically disclosed.

The tertiary reference discloses personal care compositions containing up to 1 percent by weight of the hydrochloric salt of ethyl lauroyl arginine (LAE) as an antimicrobial agent. See the first paragraph of p. 4, and see also working example 4 at p. 12 in which an aqueous oral care composition (liquid dentifrice) comprising a surfactant (sodium lauryl sulfate), a mixed polyhydric alcohol humectant (glycerol and sorbitol) and water is specifically prepared. The reference further teaches that LAE provides synergistic antimicrobial activity. See p. 2, lines 11-14 and p. 3, lines 20-27. Accordingly, it would have been obvious to have used LAE as the cationic antimicrobial agent suggested by the combined teachings of the primary and secondary references, motivated by the desire to provide optimum antimicrobial activity as taught by the tertiary reference.

Provisional Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 14 and 16 of copending Application No. 10/875,063. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the instant claims is clearly sub-generic to that of the specified conflicting claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2) Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-12, 17, 18 and 22-25 of copending Application No. 10/875,063 in view of Beltran et al (WO 03/043593).

The subject matter of the instant claims is clearly sub-generic to that of the specified conflicting claims, and also differs therefrom insofar as specific arginine ester salts must be selected as the generally recited "cationic compounds" of the conflicting claims to arrive at the instantly claimed subjected matter.

The secondary reference discloses personal care compositions containing up to 1 percent by weight of the hydrochloric salt of ethyl lauroyl arginine (LAE) as an antimicrobial agent. The reference

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further teaches that LAE provides synergistic antimicrobial activity. See p. 2, lines 11-14 and p. 3, lines 20-27. Accordingly, it would have been obvious to have used LAE as the cationic compound of the generic conflicting claims, motivated by the desire to provide optimum antimicrobial activity as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

